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**BY HAND DELIVERY**

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Comments in Response to Advance Notice of Proposed Rulemaking Concerning Medical Devices; Refurbishers, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Guides and Regulatory Requirements; Docket No. 97N-0477

Dear Sir or Madam:

The undersigned, on behalf of the Association of Medical Device Reprocessors (AMDR), respectfully submits these comments to the above-referenced Advance Notice of Proposed Rulemaking (ANPR). In this ANPR, the Food and Drug Administration (FDA) solicits comments on its proposed definitions for medical device "refurbishers," "'as is' remarketers," and "servicers," as well as on its current definition for medical device "reconditioners/rebuilders." In addition, the agency seeks comments on how these entities should be regulated.

As discussed below, in AMDR's view, none of these definitions encompasses medical device reprocessors. To the contrary, medical device reprocessing is entirely distinct from refurbishing, 'as is' remarketing, servicing, and reconditioning/rebuilding, and, as such, should be treated as a completely separate regulatory category.

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## I. Reprocessors Do Not Fit Within Any of FDA's Proposed Definitions

Medical device reprocessors are persons who inspect, functionally test, clean, package, and sterilize devices labeled for single use, at the request of a customer, in such a manner that (i) the quality, physical characteristics, and performance functions of the device are not significantly affected, and (ii) the device remains safe and effective for its appropriate clinical use. Reprocessors do not take title to devices, but, rather, simply return reprocessed devices to the customer/owner of the device that requested reprocessing.

Reprocessors differ significantly from the four entities that FDA addresses in the above-referenced ANPR. For example, under the agency's current definition, a "reconditioner/rebuilder" is a "person or firm that acquires ownership of used medical devices and restores and/or refurbishes these (devices) to the device manufacturer's original or current specifications, or new specifications, for purposes of resale or commercial distribution." 62 Fed. Reg. 67011 (emphasis added). Reprocessors clearly do not come within this definition of "recondtioner/rebuilder," because they neither take ownership of the devices that they reprocess, nor do they resell or commercially distribute devices.

FDA proposes to define "refurbishers" as "persons who, for the purposes of resale or redistribution, visually inspect, functionally test and service devices, as may be required, to demonstrate that the device is in good repair and performing all the functions for which it is designed. . . ." 62 Fed. Reg. 67012 (emphasis added). This definition of "refurbisher" does not encompass reprocessors, because reprocessors do not resell or redistribute devices. Likewise, FDA proposes to define "'as is' remarketer" as follows:

> [F]or the purpose of resale or distribution, the operational condition of the device is unknown. The extent to which the device meets the operational requirements must be determined by the user prior to patient exposure. The device may or may not be cosmetically enhanced. 'As is' remarketers do not change a finished device's performance or safety specifications, or intended use.

Id. (emphasis added). Again, reprocessors do not come within the definition of "'as is' remarketer" because reprocessors do not engage in resale or redistribution. Furthermore, as a matter of common sense, reprocessors are not "'as is' remarketers," because they do not remarket devices 'as is.' Rather, they reprocess devices and return them to their original owner.

Finally, FDA's proposed definition of "servicer" does not encompass reprocessors. As contemplated by the agency, "servicers" are

> persons who repair a device to return it to the manufacturer's fitness for use specifications, and perform the manufacturer's recommended scheduled preventive maintenance. Servicers do not significantly change a finished device's performance or safety specifications, or intended use.

Id. (emphasis added). Reprocessors do not "perform the manufacturer's recommended scheduled preventive maintenance," and, as such, are not "servicers."

## II. Reprocessors Should Be Regulated As An Entirely Separate Entity

Given that reprocessors are demonstrably different from "reconditioners/rebuilders," "refurbishers," "'as is' remarketers," and "servicers," they should be regulated as an entirely separate entity, distinct from any of these groups. In AMDR's view, reprocessors should be subject only to establishment registration requirements[1], Quality System Regulation (QSR) requirements (excluding design controls), and medical device reporting (MDR) requirements. Device marketing authorization requirements, i.e., premarket notification requirements (set forth in 21 C.F.R. Part 807, Subpart E) and premarket approval requirements (set forth in 21 C.F.R. Part 814), should not be imposed on reprocessors.

Indeed, under the Federal Food, Drug, and Cosmetic Act (FDC Act), FDA lacks the statutory authority to impose device marketing authorization requirements on persons who reprocess medical devices labeled for single use, when the devices are received from and returned to the same party requesting reprocessing. Furthermore, requiring reprocessors to obtain marketing authorization would constitute an irrational departure from longstanding agency policy. Historically, FDA has not enforced the FDC Act's device marketing authorization requirements

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[1] With respect to the appropriate registration status for reprocessors, FDA's establishment registration form, i.e., form FDA 2891, currently contemplates 11 different types of establishments: certifying site/MDR reporting site, contract manufacturer, manufacturer, repacker and/or relabeler, specification developer, contract sterilizer, U.S. designated agent, remanufacturer, initial distributor, refurbisher, and reconditioner. Given that reprocessors do not fit into any of these categories, form FDA 2891 should be modified to include a separate designation for reprocessors.

with respect to entities such as reprocessors, who do not take title to a medical device or cause its distribution to a new party. For example, FDA has never required contract manufacturers or contract sterilizers to obtain device marketing authorization for the purpose of returning product to the finished device manufacturer. Thus, a decision by FDA to require reprocessors to obtain device marketing authorization prior to returning a reprocessed device to a party who requested reprocessing, would be an arbitrary and capricious action in violation of the Administrative Procedure Act, because FDA does not impose this requirement on similarly-situated parties. Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20 (D.D.C. 1997).

AMDR is aware that FDA is in the process of evaluating the level of regulatory control that is appropriate for reprocessors. Significantly, regardless of whether FDA ultimately imposes registration, QSR, and MDR requirements on reprocessors, AMDR members are fully committed to registering their establishments and complying with MDR and QSR requirements (excluding design controls) on a voluntary basis. However, AMDR strongly opposes the imposition of device marketing authorization requirements on reprocessors. Indeed, as described above, FDA lacks the statutory authority to impose such requirements on reprocessors, and to do so would constitute an unlawful and unreasonable departure from longstanding agency policy.

In sum, neither FDA's proposed definition of "refurbisher," "'as is remarketer,'" or "servicer," nor its current definition of "reconditioner/rebuilder" encompasses medical device reprocessors. Reprocessing is distinct from each of these activities, and, as such, reprocessors should be defined and regulated as an entirely separate entity.

Respectfully submitted,

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